

# Telemedicine Standards Development Framework



An Initiative of the  
American Telemedicine Association



# Objective: A Clear Road Map for the development of Telemedicine Standards



- Patient Safety
- Quality of Care
- Balance
  - Measurable
  - Cost Effective
  - Evidence based
  - Realistic



# Definition of Standards (ISO)

1. Document that prescribes requirements to be fulfilled by a product, process, or service
2. Document established by consensus and approved by a recognized body that specifies requirements to be fulfilled by a product or a group of products, to establish its fitness for purpose



# ATA Standards Definition

**Standard:** A statement established by consensus or authority that provides a benchmark for measuring quality and that is aimed at achieving optimal results (NIFTE Research Consortium, 2003)

**Guideline:** A statement of policy or procedure by which to determine a course of action or give guidance for setting standards (adapted from Ioane & Wootton 2002)



# Standards Development Organization Advancement Act of 2003

A *standards development organization* is an organization "that plans, develops, establishes, or coordinates voluntary consensus standards" in a way that, in accordance with OMB Circular Number A-119, as revised February 10, 1998, is open (with notice to all affected parties), includes:

- A balance of interests (so that no single group of interested persons dominates the process)
- Affords participation in standards development or modification
- Allows easy access to essential information regarding proposed and final standards,
- Achieves consensus (not necessarily unanimity), and assures due process, including appeals procedures.

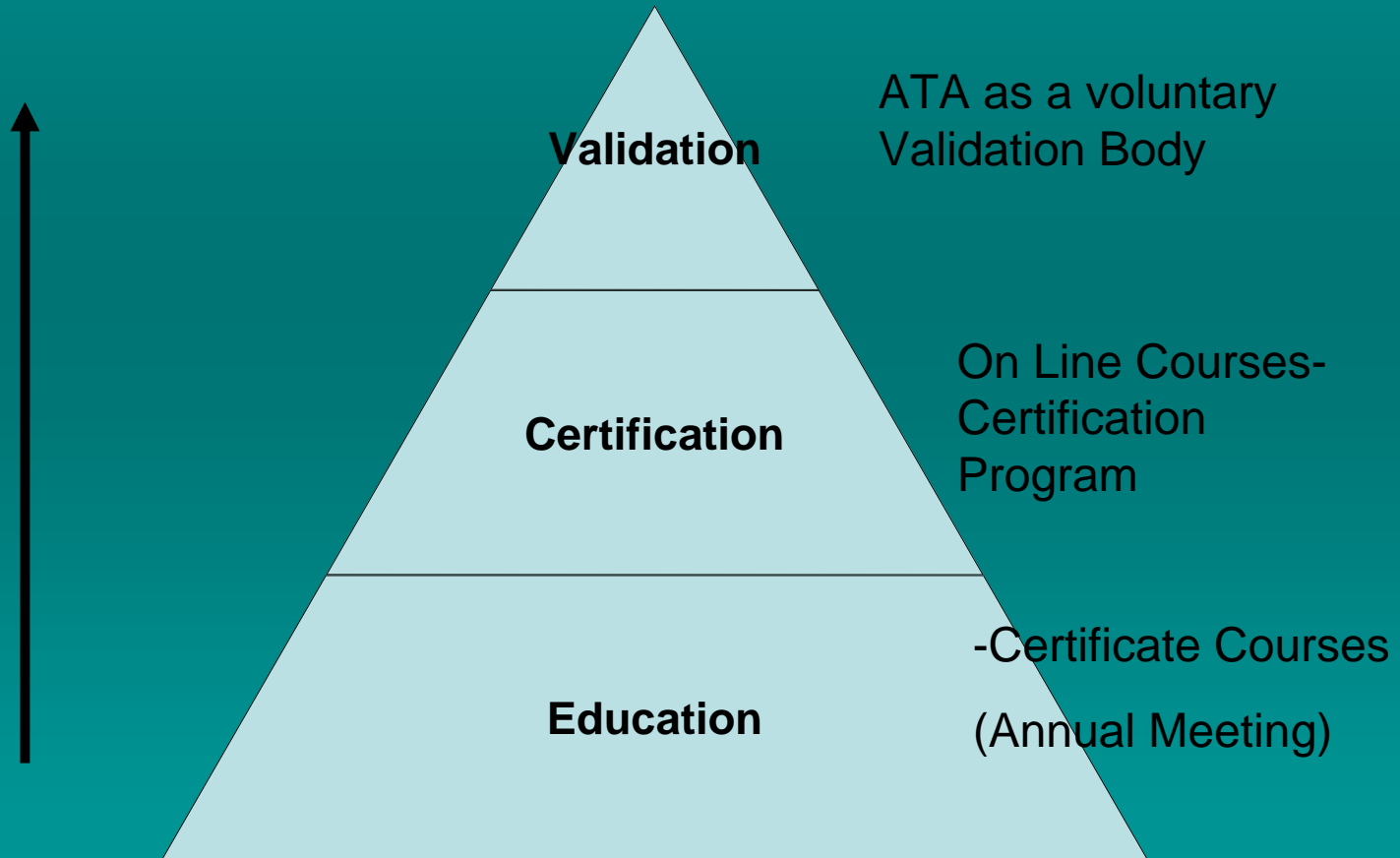


# ATA Accomplishments

- 1<sup>st</sup> Standards/Report focused on Diabetic Retinopathy 2005 (NIST-ATA)
- Definitions and Nomenclature (Near completion)
- Generic Use Case Development (On going). Validation of Use cases in collaboration with Continua
- Drafting an overarching Telemedicine Standards Paper (Ongoing)
  - Modeled Canadian Telehealth Position Paper
- Formalize framework for standards development (By March 2007)
- Teledermatology Standards Working Group Meeting (14 Dec 2006)
- Development of certificate courses in targeted specialty areas (Home Health)



# ATA Standards Roadmap





# Definition: Certificate Program

- Completion of a Program/Education
  - Attendance of Annual or Regional Meeting
- Attendance not measure of competence or proficiency



# Certification Program

- A formal process of making certain that an individual is qualified in terms of particular knowledge or skills.
- Certification programs are often fostered or supervised by some certifying agency, such as a professional association.
- Examples: Some major computer software and hardware vendors provide a certification program for installers of their product, such as Microsoft's Certified Systems Engineer ([MCSE](#)) for its Windows operating systems, IBM's Certified Lotus Specialist (CLS), and Cisco's Certified Internetwork Professional (CCIP).



# Definition: Accreditation

- To evaluate their services and to better the quality of their services.
- *The act of granting credit or recognition of meeting some national “standards” of quality*
- *A formal validating process and organization*
- *Example: JCAHO*



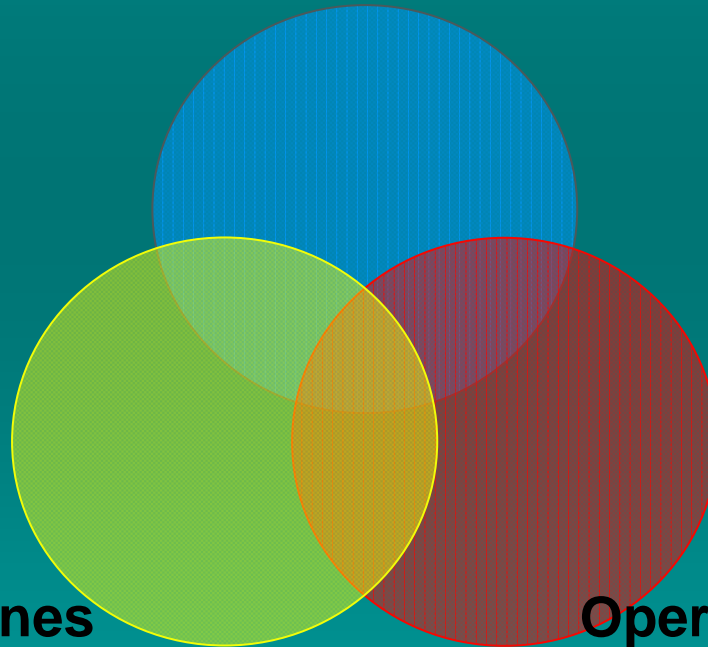
# Credentialing and Privileging

The Joint Commission for Accreditation of Health Care Organizations (JCAHO) has adopted standards for telemedicine. Practitioners who render care using live/interactive systems are subject to credentialing and privileging at the distant site when they are providing direct care to the patient. The originating site may use the credentialing and privileging information from the distant site if all the following requirements are met: (i) the distant site is JCAHO-accredited; (ii) the practitioner is privileged at the distant site for those services that are provided at the originating site, and the originating site has evidence of an internal review of the practitioner's performance of these privileges and sends to the distant site information that is useful to assess the practitioner's quality of care, treatment, and services for use in privileging and performance management.



# ATA Proposed Telemedicine Standards Framework

Technical Standards



Clinical Guidelines

Operational Guidelines



# Use Cases

Development of a taxonomy/classification of telemedicine that is decomposed to the level of granularity necessary to identify (1) commonality and (2) variability/uniqueness of particular telemedicine applications

Lays out:

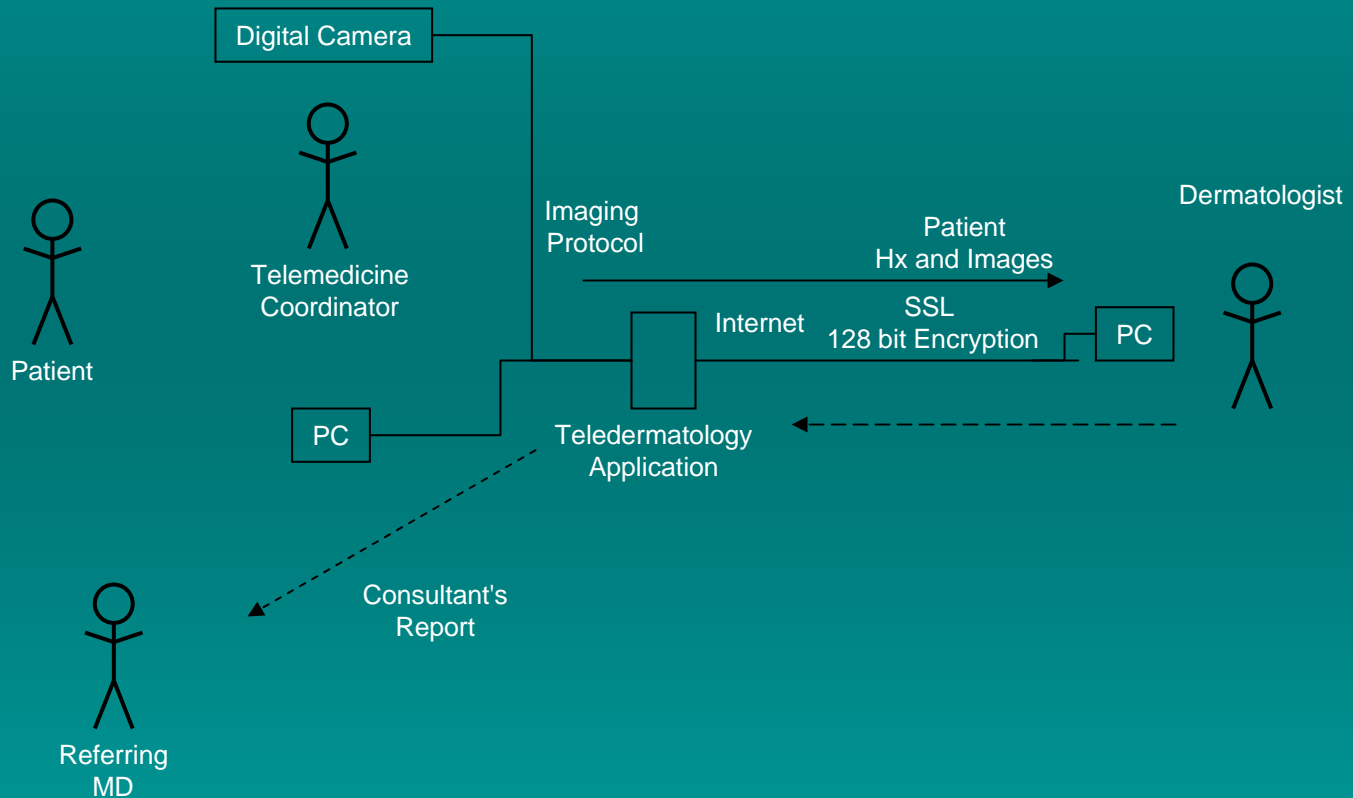
- care settings/points of care
- actors/roles
- workflow (and information flow)
- data, information, and knowledge requirements
- interfaces/intersections
- presence of existing standards and gaps in standards

Clinical, business, and workflow needs drive technical requirements



# Use Case Graphical representation

## *SAF Teledermatology consultation*





# Practice guidelines



## Technical and Interoperable Standards

### Topics

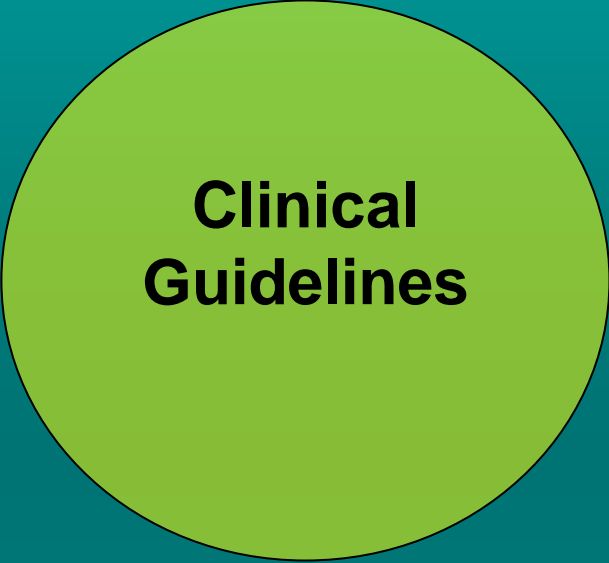
- Data acquisition & display validation
- Transmission
- Storage/archive
- Security
- Existing standards

### Process

- Identify appropriate standards organizations
- Identify applicable standards
- Develop new technical standards when appropriate in conjunction with NIST and other organization



# Practice guidelines



## Clinical Guidelines

### Topics

- Minimal clinical data set
- Imaging protocol
- Inclusion/exclusion criteria
- Develop use cases

### Process

- Identify and coordinate with specialty organizations
- Identify existing standards
- Develop new or modify standards for telemedicine in collaboration with specialty organizations



# Practice guidelines



## Administrative Rules and Business Models

### Topics

- Policy
- Training
- Procedures
- Certification
- Business model

### Process

- Develop guidance on procedures (SOP)
- Develop training requirements
- Develop guidance on policy
- Develop guidance on a certificate program
- Identify appropriate business models



ATA  
BoD

# Technical Standards & Practice Guidelines Development Oversight

ATA  
Standards and Guidelines  
Committee

NIST

Industry Council

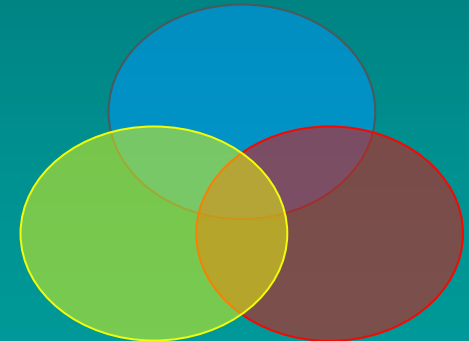
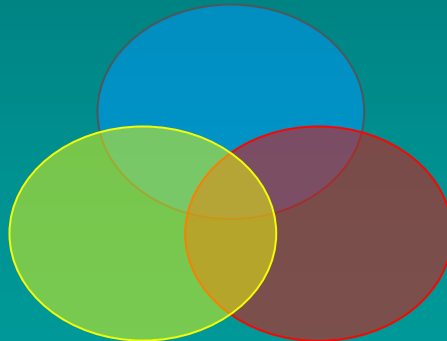
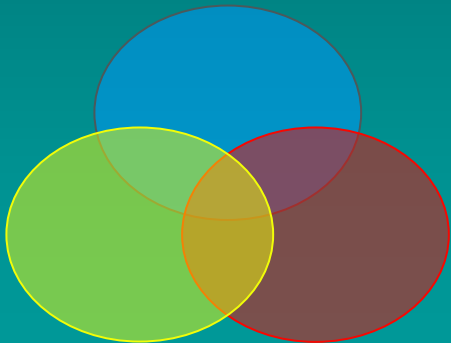
Tech & Human  
Factors  
SIG's

Policy Committee  
& Nursing SIG

Tele Dermatology SIG

Home Tele Health SIG

Tele Mental Health SIG





# Proposed Process for Development

## **Step 1: Guideline Scope and Definition – Preparation Workshop**

- a. Review ATA standards/guideline paper
- b. Develop consensus on scope and definitions and use cases
- c. Identification of existing clinical benchmark reference or “as is” Gold standards
- d. Identification of stakeholder membership
- e. Catalogue of existing standards or guidelines available

## **Step 2: Stakeholder Forums/Workshops –information and knowledge collection**

- a. Clinical Forum
- b. Technical Forum
- c. Operational/Administrative Forum

## **Step 3: Forum Section Author Teams – initial section draft process**

## **Step 4: On-line Comment Period by stakeholder groups**



# Proposed Process for Development

**Step 5: Guideline document integration by Editorial Board**

**Step 6: Final Document published for open comments**

**Step 7: Approval by ATA and endorsement by external societies**

**Step 8: Development of education and implementation Strategy related to best practices and guidelines**

**Step 9: Development of certification program**

**Step 10: Guideline Update Review and Revision -Annually**



# Standards Development Guidelines

- **Disclosure:** A disclosure form will be provided to each member of the workgroups that are involved in standards and guidelines. Participants will be asked to fully disclose any potential conflicts. This information will be shared with other members of the work group and be made public.
- **Fair representation** of members from clinical, industry, government and other potentially affected parties.
- **A notice** should be circulated publicly that ATA is forming these work groups with information about their purpose, process, timelines and proposed products. Anyone from the affected parties, regardless of ATA membership status, will be able to attend a future meeting of the work group (but they would not necessarily have a voice at the table or a vote).
- **Transparent Process:** The proposed and final documents will be made available on the ATA website for open comment. Once adopted, a simple process will be developed to allow for appeals of the final rule.



# Contributions

- Standards Committee
- NIST
- AAD
- ATA Staff



# Comments

- Feedback
  - Framework
  - Process